

REMARKS

Applicants have carefully considered this Application in connection with the Examiner's Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Claims 1-9, and 11-47 are pending in this application.

Claim 1 has been amended to clarify the terms "mono-disperse nanoparticles" and "mono-dispersed polymer."

Claim 1 has been amended to recite, "wherein the aqueous dispersion exhibits a change in particle size of less than 30 nm when the aqueous dispersion is heated from below a volume phase transition temperature to above a volume phase transition temperature at a concentration of 2.88×10^{-5} g/ml." This is supported throughout the specification, especially in Figure 5 and paragraph [0161].

Claim 15 has been amended to recite, "wherein the second temperature is below the low critical solution temperature of the first monodispersed polymer." This is supported throughout the specification, especially in paragraphs [0056], [0070], and [0083].

Claim 29 has been amended to recite, "wherein the IPN nanoparticles exhibit a change in particle size of less than 30 nm when the IPN nanoparticles are heated from below a volume phase transition temperature to above a volume phase transition temperature at a concentration of 2.88×10^{-5} g/ml." This is supported throughout the specification, especially in Figure 5 and paragraph [0161].

I. CLAIM REJECTIONS UNDER 35 USC §112

The Examiner has rejected Claims 15-28 on the grounds that Claim 15 is confusing due to the terms “mono-disperse nanoparticles” and “a mono-dispersed polymer.” Applicants have clarified the claim language, and believe that this will overcome the Examiner’s rejection.

II. CLAIM REJECTIONS UNDER 35 USC §102

The Examiner has rejected Claims 15, 20-27, under 35 U.S.C. 102(b) as being anticipated by Jones et al. *Macromolecules*, 2000, Vol. 33, p. 8301-8306 (“the Jones Reference”).

Applicants have amended Claim 15 to recite a second temperature which is lower than the lower critical solution temperature (LCST) of the first mono-dispersed polymer.

The Jones Reference teaches adding a second monomer, and reacting at a temperature of 70°C, which is above the LSCT of the first polymer taught in the Jones Reference. Specifically, p. 8302, first column, first paragraph, teaches, “The *p*-NIPAm core solution (150 mL volume) was heated and maintained at 70 °C for 15 min at a maximum stir rate in a 500 mL three-neck, round-bottom flask, after which 30 mL of the NIPAm + AAc shell solution was added. *After reacting for 30 min at 70 °C*, the remaining 170 mL of shell solution was added in 10 mL aliquots via a syringe over a period of 45 min. *The reaction was allowed to proceed at a temperature of 70 °C for 6 h.*”

Therefore, because the Jones References does not teach each and every element of the claims, as amended, it cannot be said to anticipate the current claims.

III. CLAIM REJECTIONS UNDER 35 USC §103

A. Claims 1-9 and 11-28 over Jones in view of Kurisawa, in further view of Cai

The Examiner has rejected Claims 1-9 and 11-28 under 35 U.S.C. 103(a) as being unpatentable over the Jones Reference in view of Kurisawa et al. *Journal of Controlled Release*,

1998, Vol. 54, p. 191-200 (“the Kurisawa Reference”) and further in view of over Cai et al. *Journal of Applied Polymer Science*, 2002, Vol. 83, p.169-178 (“the Cai Reference”).

The Examiner states that a person of ordinary skill in the art would have been motivated to modify the method and dispersion of hydrogel nanoparticles as taught by the Jones Reference with the teachings of the Kurisawa Reference regarding adding a drug at a third temperature below a gelation temperature of the IPN nanoparticles in an aqueous mixture, and to modify the phase transition properties of the IPNs by varying the ratios of the component monomers according to the teaching of the Cai Reference. Applicants respectfully disagree with the Examiner’s assessment.

In order to more clearly differentiate the compositions, Applicants have amended Claim 1 to recite “wherein the aqueous dispersion exhibits a change in particle size of less than 30 nm when the aqueous dispersion is heated from below a volume phase transition temperature to above a volume phase transition temperature at a concentration of 2.88×10^{-5} g/ml.”

The Jones Reference teaches a distinct composition and method from the current claims, as amended. Current Claims 1-9, and 11-14, recite an aqueous dispersion which is distinct from the weakly interpenetrating polymer network of the Jones Reference in that the currently claimed dispersion shrinks less above the volume transition temperature than a PNIPAM network such as the one taught in the Jones Reference. This is shown in Figure 5 and paragraph [0061] of the current specification. Claims 15-28 recite a method wherein the reaction mixture is cooled to a second temperature below the low critical solution temperature of the first monodispersed polymer. There is no teaching in the Jones Reference of cooling the reaction mixture, or of the distinct properties which result from this method.

The Examiner has stated that the Kurisawa Reference teaches IPN-structured hydrogels as a drug reservoir, and that drug release was achieved in the IPN-structured hydrogels prepared below gel transition temperature. However, drug release in the Kurisawa Reference is achieved through enzymatic degradation, and does not involve a reversible phase transition as is required by the

current claims. Therefore, there is no teaching in Kurisawa which would lead one of skill in the art to practice the currently claimed method and the aqueous dispersion which is produced by this method.

The Examiner has stated that the Cai Reference teaches that the combined properties of hydrogels can be controlled by the ratios of their components. This would not suggest the current method, or aqueous dispersion, which is achieved through manipulation of temperature during formation of the aqueous dispersion.

Therefore, none of the cited references could have been combined with the knowledge of one of skill in the art to arrive at the currently-claimed method or aqueous dispersion.

B. Claims 29-47 over Cai in view of Jones, in further view of Hennink & Nostrum

The Examiner has rejected Claims 29-47 over the Cai Reference, in view of the Jones Reference, and in further view of Hennink and Nostrum *Advanced Drug Delivery Reviews*, 2002, Vol. 54, p. 13-36 (“the Hennink Reference”).

As described in detail above, the Cai Reference and the Jones Reference fail to disclose either the step of cooling the reaction mixture to a second temperature below the low critical solution temperature of the first monodispersed polymer, or an aqueous dispersion which exhibits a change in particle size of less than 30 nm when the aqueous dispersion is heated from below a volume phase transition temperature to above a volume phase transition temperature at a concentration of 2.88×10^{-5} g/ml. Therefore, these references would not have suggested or motivated one of skill in the art to practice the invention recited in the amended claims.

Applicants have amended Claim 29 to recite “wherein the IPN nanoparticles exhibit a change in particle size of less than 30 nm when the IPN nanoparticles are heated from below a volume phase transition temperature to above a volume phase transition temperature at a concentration of 2.88×10^{-5} g/ml.”

The Examiner has stated that the Cai Reference teaches that to increase the volume and surface area of the bulk gels, hydrogels can be synthesized at temperatures above the LCST of the polymer by heating the reaction near the end of the polymerization (see Office Action of June 22, 2009, p. 15). However, there is no teaching in the Cai Reference which would suggest or motivate one of skill in the art to cool the reaction mixture to below the LCST of the first monodispersed polymer, as described in the current claims, as amended.

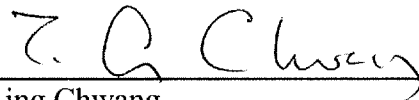
The Hennick Reference is cited by the Examiner to provide cross-linking agents, but fails to provide the missing step of cooling the reaction mixture to below the LCST of the first monodispersed polymer, or the resulting properties of the composition. Therefore, none of the references cited, alone or in combination, would have motivated one of skill in the art to practice the currently claimed invention.

IV. Conclusion

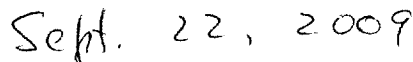
Applicants respectfully submit that, in light of the foregoing comments and amendments, all pending claims are now in condition for allowance. A Notice of Allowance is therefore requested.

If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,



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Date